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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,773	05/13/2005	John Forsyth Russell Robertson	49409-0041 (315804)	1789
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JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER BRISTOL, LYNN ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 12/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,773	Applicant(s) ROBERTSON ET AL.	
	Examiner Lynn Bristol	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007 and 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-8, 11, 12 and 15-18 are all the pending claims for this application.
2. The Examiner gratefully acknowledges the revised claim set filed 10/12/07 in response to the Notice of Non-Compliant Amendment of 9/12/07. Claims 1-8, 11 and 12 were amended, Claims 9 and 10 were cancelled and Claims 17 and 18 withdrawn in the Response of 10/12/07. Applicants' remarks to the outstanding objections and rejections presented in the Response of 7/5/07 herein form the basis of the examination of the pending claims.
3. Claims 15 and 16 are withdrawn from examination.
4. Claims 1-8, 11 and 12 are all the pending claims under examination.
5. **This action is FINAL.**

Withdrawal of Objections

Oath/Declaration

6. The objection to the oath or declaration for containing non-initialed and/or non-dated alterations is withdrawn.

Applicants' submission of a newly executed Oath/Declaration with the Response of 7/5/07 is entered.

Specification

7. The objection to the specification on p. 1 of the file copy because of alterations which have not been initialed and/or dated as required by 37 CFR 1.52(c) is withdrawn in view of the amendment of the specification on p. 2 of the Response.

8. The objection to the specification for failing to cross-reference related applications is withdrawn in view of the amendment to the specification on p. 2 of the Response.

9. The objection to the improper use of the trademarks, e.g., PinPoint TM, is withdrawn in view of the amendments to the specification on pp. 2-4 of the Response.

Claim Objections

10. The objection to Claim 2 (2nd "wherein" clause) for reciting duplicate claim language- "of" is withdrawn in view of the amendment of Claim 2 to delete the duplicate recitation.

11. The objection to Claims 11, 13 and 17 as depending from non-elected claim 10 is withdrawn for Claim 11 in view of its amended dependency from Claim 1, and withdrawn and moot for cancelled Claims 13 and 17.

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, second paragraph

12. The rejection of Claims 13, 14, 17 and 18 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is withdrawn and moot for cancelled Claims 13 and 14 and withdrawn in view of the withdrawal of Claims 17 and 18 from examination.

13. The rejection of Claims 13, 14, 17 and 18 for the recitation "one or more tumor marker protein prepared from a bodily fluid, derived from a body cavity or space" is withdrawn and moot for cancelled Claims 13 and 14 and withdrawn in view of the withdrawal of Claims 17 and 18 from examination.

14. The rejection of Claims 1-8, 11-14, 17 and 18 for the recitation "with which is or was associated" is withdrawn and moot for cancelled Claims 13 and 14, withdrawn in view of the withdrawal of Claims 17 and 18 from examination, and withdrawn for Claims 1-8, 11 and 12 in view of the deletion of the phrase from claim 1.

15. The rejection of Claims 2-8 and 11-14, 17 and 18 for the recitation "one or more of detecting or quantitatively measuring a presence of two or more types of autoantibodies" is withdrawn and moot for cancelled Claims 13 and 14, withdrawn in view of the withdrawal of Claims 17 and 18 from examination, and withdrawn for Claims 1-8, 11 and 12 in view of the deletion of the phrase from claim 2.

16. The rejection of Claims 2-8 and 11-14, 17 and 18 for the recitation "or to of same tumor marker protein" in Claim 2 (1st "wherein" clause) is withdrawn and moot for cancelled Claims 13 and 14, withdrawn in view of the withdrawal of Claims 17 and 18 from examination, and withdrawn for Claims 2-8, 11 and 12 in view of the amendment of claim 2 to recite that the autoantibodies are immunologically specific "to different epitopes of the same tumor marker protein".

17. The rejection of Claims 17 and 18 for reciting improper Markush group language is withdrawn in view of the withdrawal of Claims 17 and 18 from examination.

Claim Rejections - 35 USC § 102

18. Claims 1-8, 11-14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Robertson et al. (WO 99/58978; published November 18, 1999; cited in the PTO form-892 of 9/27/06) is withdrawn.

The rejection is withdrawn and moot in view of cancelled claims 13 and 14, and withdrawn for withdrawn Claim 17 and 18. Applicants' allegations on p. 11 of the Response that Robertson does not "isolate tumour marker proteins from a bodily fluid obtained from a body cavity or space where a tumor is or was present or associated" and that pleural effusions were not a source of marker proteins but instead provided clinical evidence of other malignancies obviates the rejection over Robertson.

19. The rejection of Claims 1, 3, 4, 11 and 12 under 35 U.S.C. 102(b) as being by anticipated by Luo et al. (British J. Can. 87:393-343 (7/29/2002); cited in the PTO form-892 of 9/27/06) is withdrawn.

Applicants allege "the immunoassay reagents taught by Luo are the hsp90 proteins encoded by the cDNA library"...and "these immunoassay reagents were not isolated from bodily fluid obtained from a body cavity or space in which a tumor is or was present or associated."

Luo discloses a premade ovarian carcinoma cDNA expression library from Stratagene (p. 340, Col. 1, Materials & Methods). Luo does not disclose how the ovarian carcinoma cDNA library was made, whether it was obtained from a bodily fluid, and therefore it is indeterminate whether the hsp90 protein was "prepared from a bodily fluid derived from a body cavity or space" in which an ovarian carcinoma is or was present or associated with an ovarian cancer patient.

The Examiner's search of the on-line Stratagene catalog of reagents did not reveal any information pertaining to the Uni-ZAP ovarian carcinoma cDNA library that would suggest whether the cells were prepared from a bodily fluid.

Double Patenting

20. The provisional rejection of Claims 13, 14, 17 and 18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 8 and 9 of copending Application No. 10/417,633 ("the '633" application; US 20030232399) in view of Robertson et al. (WO 99/58978; published November 18,

1999; cited in the PTO form-892 of 9/27/06) is withdrawn and moot for cancelled Claims 13 and 14 and withdrawn in view of the withdrawal of Claims 17 and 18.

21. The provisional rejection of Claims 13-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 8, 19, 20 and 24 of copending Application No. 09/881,339 ("the '339" application; US 20030138860) in view of Robertson et al. (WO 99/58978; published November 18, 1999; cited in the PTO form-892 of 9/27/06) is withdrawn and moot for cancelled Claims 13 and 14, and withdrawn and moot for withdrawn Claims 15-18.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. The rejection of Claims 1-8, 11 and 12 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained.

The omitted steps are the relationship between the sample on which the method steps are being performed and the tumor marker proteins "derived" from bodily fluids or excretions from one or more cancer patients. In other words, the claims do not describe

whether the cancer patients from which the reagents are derived would also have the same or a similar cancer (e.g., stage) as the individual being tested.

Applicants have not addressed this rejection in their Response of 7/5/07.

23. The rejection of Claims 1-8, 11 and 12 for the recitation "one or more tumor marker protein prepared from a bodily fluid, derived from a body cavity or space" because in Claim 1 (1st "wherein" clause) the meaning of the term "derived" is not clear. The term "derived" is not one which has a universally accepted meaning in the art nor is it one which has been adequately defined in the specification. The primary deficiency in the use of this term is the absence of an ascertainable meaning. Since it is unclear how the bodily fluids are to be derived from a body cavity or space, the term can encompass body fluids that are pre-filtered or pre-adsorbed or which have undergone any number of different steps after being removed from the body cavity or space prior to the protein then being prepared from the fluid sample. Would the "prepared" tumor protein be any different than the protein found in the fluid of a body cavity or space?

Applicants have not addressed this rejection in their Response of 7/5/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanash et al. (WO 00/26668; published 5/11/2000; cited in the IDS of 12/14/06) is maintained.

Applicants allege on p. 12 of the Response that Hanash "fails to teach isolation of tumor marker proteins from a bodily fluid at all and certainly fails to teach the isolation of tumor marker proteins from a biological fluid obtained from a body cavity or space in which a tumor is or was present or associated."

Hanash teaches immunoassay methods for detecting autoantibodies in samples against cancer or tumor-derived family of S100 proteins where the S100 proteins are obtained from bodily fluids or a wide variety of protein mixtures containing S100 proteins (p. 6, lines 3-16; p. 6, line 30 to p. 7, line 1) or serum (p. 7, line 4; p. 10, lines 10-21) See also p. 11, lines 1-11.

Hanash discloses four S100 proteins, specifically, S 100-AG, S 100-A7, S 100-A8 and S100-A9, and using these isolated proteins in immunoassays for detection of autoantibodies (Example 7).

Hanash discloses using the methods for detection and quantitative measurement of S100 autoantibodies and in screening subjects for risk of cancer or other proliferative diseases (p. 6, lines 9-12) or for the early diagnosis of diseases such as cancer or monitoring of autoantibody levels to prognostically to stage the progression of the disease (p. 11, lines 1-4) or monitoring the efficacy of various therapeutic treatments for cancer (p. 4, line 1 p. 5, line 1).

One skilled in the art could readily envisage that the body fluids or biological fluids of Hanash could readily be obtained from a body cavity or space where any of the disclosed cancers is present, was present or is associated within. For example, Hanash teaches that breast cancer cells secrete S100-A7 and S100-A8 proteins (p. 10, line 13-15) thus secretion of the tumor marker into a compartment associated with the cancer such as a duct or cyst or hydrocoele would be inherent to the pathology of the disorder and obtaining the bodily fluid well within ordinary skill. Further, one skilled in the art could readily consult any online medical dictionary (Steadman's Medical Dictionary- see attached definition of "fluid") to understand that a common meaning of the term "fluid" could comprise a fluid from a body space such as allantoic cavity, alveolar space, choroid plexus, interstitial, pleural, ventricular, etc. Thus contrary to Applicant's assertion, in Example 7 Hanash shows that a tissue sample can be prepared and the tumor proteins isolated by 2-D gel electrophoresis followed by membrane transfer and blotting with serum from a patient to determine the presence of autoantibodies.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. The provisional rejection of Claims 1-8, 11, and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 8 and 9 of copending Application No. 10/417,633 ("the '633" application; US 20030232399) in view of Robertson et al. (WO 99/58978; published November 18, 1999; cited in the PTO form-892 of 9/27/06) is maintained.

Applicants state on p. 13 of the Response that they wish to defer filing a Terminal Disclaimer until allowable subject matter in the '633 application is established, and they have not done so.

26. The provisional rejection of Claims 1-8, 11 and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 8, 19, 20 and 24 of copending Application No. 09/881,339 ("the '339" application; US 20030138860) in view of Robertson et al. (WO 99/58978; published November 18, 1999; cited in the PTO form-892 of 9/27/06) is maintained.

Applicants state on p. 13 of the Response that they wish to defer filing a Terminal Disclaimer until allowable subject matter in the '339 application is established, and they have not done so.

Conclusion

27. No claims are allowed.

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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